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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,571	01/29/2004	Karla Weaver	10123/00701	6350
7590 Patrick J. Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038				
EXAMINER				
STIGELL, THEODORE J				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
12/08/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/768,571

**Applicant(s)**

WEAVER ET AL.

**Examiner**

THEODORE J. STIGELL

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 12-14, 16-18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-14, 16-18, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 10, 12-14, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (4,447,237) in view of Merrill et al. (3,673,612). Frisch discloses most of the limitations recited in the claims listed above but fails to explicitly disclose that the nonthrombogenic coating includes hydrogel. The examiner first notes that such a limitation is a mere design consideration as the applicant has not disclosed that a hydrogel coating works better than any other coating or solves a problem that other coatings are not capable of solving. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use hydrogel, since it has been held to be within the general skill of a worker in the art to select a known material

on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Furthermore, Merrill discloses an anticoagulant coating for medical devices comprising a combination of an anticoagulant and a hydrogel. Merrill teaches that such a coating on medical devices provides many advantages such as a more uniform distribution of heparin and lower costs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Frisch with the coating of Merrill to make a more efficient and cheap valve assembly.

Claims 8-9, 18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch *et al.* (4,447,237) and Merrill *et al.* (3,673,612) in view of Steigerwald (5,009,391). Frisch and Merrill disclose most of the limitations recited in the independent claim but fail to disclose abutting flexible membranes. Steigerwald teaches abutting two flexible membranes adjacent to one another. (See Fig. 4d.) Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Frisch and Merrill with the teachings of Steigerwald to provide a valve with abutting flexible membranes.

Claims 18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steigerwald (5,009,391) in view Merrill *et al.* (3,673,612). Steigerwald discloses most of the limitations recited in the claims listed above but fails to explicitly disclose a nonthrombogenic coating that includes hydrogel.

Merrill discloses an anticoagulant coating for medical devices comprising a combination of an anticoagulant and a hydrogel. Merrill teaches that such a coating on

medical devices provides many advantages such as a more uniform distribution of heparin and lower costs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Frisch with the coating of Merrill to make a more efficient and cheap valve assembly capable of providing an anticoagulant capability.

Claims 1-10, 12-14, 16-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being obvious over Weaver et al. (US 2004/0267185) in view of Merrill et al. (3,673,612). Weaver discloses a pressure activated valve comprising a valve housing (18, 20), a flexible membrane (100) disposed in the valve housing, the membrane including a slit (112) extending through the housing so that the membrane may be moved between an open and closed configuration based on fluid pressure delivered by a dialysis machine. Weaver does not teach to include a nonthrombogenic coating made of a hydrogel on the contacting surfaces of the membrane.

Merrill discloses an anticoagulant coating for medical devices comprising a combination of an anticoagulant and a hydrogel. Merrill teaches that such a coating on medical devices provides many advantages such as a more uniform distribution of heparin and lower costs.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Weaver et al. with the coating of Merrill to make a more efficient and cheap valve assembly capable of providing an anticoagulant capability.

Claims 1-10,12-14,16-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being obvious over Moorehead et al. (US 2005/0048555) in view of Merrill et al. (3,673,612). Moorehead discloses a pressure activated valve comprising a valve housing (15), a flexible membrane (24) disposed in the valve housing, the membrane including a slit (26) extending through the housing so that the membrane may be moved between an open and closed configuration based on fluid pressure delivered by a dialysis machine. Moorehead does not teach to include a nonthrombogenic coating made of hydrogel on the contacting surfaces of the membrane.

Merrill discloses an anticoagulant coating for medical devices comprising a combination of an anticoagulant and a hydrogel. Merrill teaches that such a coating on medical devices provides many advantages such as a more uniform distribution of heparin and lower costs.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Moorehead with the coating of Merrill to make a more efficient and cheap valve assembly capable of providing an anticoagulant capability.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-10, 12-14, 16-18, 20 and 21 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **THEODORE J. STIGELL** whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763